IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc., a Delaware Corporation, *et al.* Defendants.	)	Civil Action No. 04-12457 PBS

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S REPLY IN SUPPORT OF THEIR OPENING BRIEF ON CLAIM CONSTRUCTION

Dated: September 15, 2006

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

Page No.(s)

I. INTRODUCTION

DePuy Mitek's Response to Defendants' Claim Construction brief ("DePuy Mitek Resp.") does little more than repeat its accusations that defendants Arthrex's and Pearsalls's ("defendants") claim constructions ignore the plain meaning of the claim terms and import limitations from the specifications into the claims.

DePuy Mitek's "ordinary meaning" argument, as defendants have previously shown, is totally divorced from the patent teachings; it is the *Texas Digital* approach *rejected* by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (2005). Defendants' Opening Brief of Claim Construction ("Def. Open. Br.") at 10-16, . Defendants' Opposition to DePuy Mitek's Claim Interpretation Brief ("Def. Claim Opp.") at 9-12. DePuy Mitek's accusation that defendants ignore the "ordinary meaning" of the patent terms is not true; defendants determine the meaning of the disputed claim terms by considering the meaning in the context of the specification and prosecution history, just as the Federal Circuit instructed in *Phillips*.

As for DePuy Mitek's contention that defendants' claim constructions attempt to import limitations from the specification into the claims or limit the claims to preferred embodiments, defendants have also previously shown that those accusations are meritless. Defendants' proposed constructions are based on *the claims as actually issued*, while DePuy Mitek's constructions, to the extent that it looks to the specification at all, are based on language that relates to claims that were *abandoned* during prosecution. *See* Def. Open. Br. at 11-13, 17-18; Def. Claim Opp. at 4-5, 9, 14-16.

The few new things DePuy Mitek asserts in its Response suffer from the same problem as its earlier submissions – it ignores the teaching of the '446 patent. DePuy Mitek simply uses the words "weak" and "strong," gives its own meaning to these words *without considering the patent specification* and then concludes that its strained interpretation should be adopted.

II. THE CONSISTING ESSENTIALLY OF ISSUE

DePuy Mitek's sole argument is that defendants' construction of the basic and novel characteristics is based on what DePuy Mitek characterizes as "preferred embodiments." DePuy Mitek Resp. at 1. But as defendants have previously shown, what DePuy Mitek calls the preferred embodiments *are* the claims. The aspects of the specification upon which defendants rely relate to the purposes of the very materials that are specifically identified in the claims.[1] Def. Open. Br. at 17-18; Def. Opp. Br. at 4-5. Importantly and dispositively, while DePuy Mitek uses the label "preferred embodiments," it *never* disputes that the portions of the specification upon which defendants rely relate to the specific materials that became the claims.[2]

III. THE "PE" VERSUS "UHMWPE" ISSUE

DePuy Mitek tries to defend its use of extrinsic evidence of the meaning of "PE" by claiming -- falsely -- that "Arthrex argues that resort to extrinsic evidence is improper." DePuy Mitek. Resp. at 4. To the contrary, defendants straightforwardly told the Court that "*Phillips* does not *preclude* the use of extrinsic evidence, nor are defendants attempting to imply that it does." Def. Claim Opp. at 16. What defendants *did* say is that DePuy Mitek improperly uses the rejected *Texas Digital* approach because DePuy Mitek's argument begins with dictionary and other types of extrinsic evidence and only uses the patent specification as a check on its dictionary definition. Def. Open. Br. at 14-16; *see also*, Def. Claim Opp. at 9-16. DePuy Mitek never responds to defendants' actual criticism of DePuy Mitek's approach.

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[1] The broad claims (which did *not* identify any specific materials) were abandoned in favor of the claims that do identify specific materials. Def. Open Br. at 6.

[2] DePuy Mitek asserts that "Arthrex Ignored the Prosecution History." DePuy Mitek Resp. at 2. That is not true. Defendants showed in their Opposition to DePuy Mitek's Claim Construction Brief that the "reasons" for amending the claim to add the words "consisting essentially of" are irrelevant to construing the basic and novel characteristics of the claimed invention (a point that DePuy Mitek does not dispute) and that, in any event, the reasons for the amendment are not as DePuy Mitek states. *See* Def. Claim Opp. at 5-7.

DePuy Mitek's criticism of defendants' use of the Spectra brochure[3] misses the point. Defendants did not use that brochure to "pluck[] the phrase 'general purpose polyethylene.'" DePuy Mitek Resp. at 4. Rather, defendants offered the brochure as further evidence that the "PE" described in the patent is consistent with general purpose polyethylene and is inconsistent with UHMWPE and to show that industry understands that there is a difference between UHMWPE and general purpose polyethylene. Importantly, DePuy Mitek never denies that the brochure accurately reflects the differences between general purpose polyethylene and UHMWPE. DePuy Mitek Resp. at 4.[4]

Next, DePuy Mitek accuses defendants of trying to read a description of a preferred embodiment into the claims. DePuy Mitek Resp. at 4-6. But as we previously showed, defendants did no such thing. The "description" from the specification upon which defendants rely, that the first set of yarns (of which "PE" is one) are lubricious materials that are highly pliable, but weak, is the description of the materials that are specifically listed in the claims. Defendants Open. Br. at 11-13. DePuy Mitek's criticism might have some marginal validity to the *abandoned* claims that required only that there be two dissimilar fibers, but DePuy Mitek's argument has no applicability to the claims as issued, which are limited to the specific materials identified in the claims.

DePuy Mitek then makes a series of arguments designed to show that Arthrex's proposed interpretation of "PE" is based on a mischaracterization of the specification. In particular, DePuy Mitek contends that (1) the patent does not teach that the lubricious yarns are weak (DePuy Mitek Resp. at 6-7), (2) the "first-fiber forming materials" are not just for pliability

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[3] Spectra is a brand name for UHMWPE.

[4] We note that DePuy Mitek has filed a motion to preclude the use of the Spectra brochure. Under separate cover, defendants' opposition shows that that motion should be denied. In any event, there are a multiple of other sources that make essentially the same unrebutted points as the Spectra brochure. See Ex. 1 at ¶¶ 8-13, and Exhibits B and D, thereto.

(DePuy Mitek at 7-8), and (3) UHMWPE is consistent with the description of the "first fiber-forming materials" and PET is consistent with the "second fiber-forming materials." DePuy Mitek Resp. at 8-10. These arguments are essentially repeats of the arguments presented in DePuy Mitek's Opposition to Defendant's Motion for Summary Judgment. While misguided, at least these arguments are properly raised in a claim construction brief, rather than in the Opposition to Summary Judgment where DePuy Mitek tries to convert claim construction issues that are matters of law into factual disputes in a transparent attempt to defeat summary judgment.

Turning to the first argument, DePuy Mitek seems to be saying that the '446 patent did not really mean that the pliable, lubricious substances are weak, even though it *specifically states* that they were "relatively weak and unusable." DePuy Mitek Resp. at 6, citing to the '446 patent at col. 2, ll. 22-25. If there were *any* merit to DePuy Mitek's strained interpretation, why would the very next sentence of the patent teach that there is a tradeoff between braid strength and pliability? Ex. 2 at col. 2, ll. 26-28. Why would the patent teach that the lubricious materials identified as the first set of yarns need to be combined with a second, stronger yarn? *Id.* at col. 4, ll.9-40. Why does the patent state that too high a percentage of "lubricating yarns" may "adversely affect the overall strength of the braid?" *Id.* at col. 4. ll. 52-54. And why do the only tests that Ethicon chooses to report show that the lubricating yarns tested were weak? *Id.* col. 7, ll. 25-34 and Table. There is, of course, only one answer. The teachings of the '446 patent are clear; the lubricating yarns from the first set of yarns are too weak and must be combined with a stronger yarn, just as defendants previously told the Court.

DePuy Mitek next asserts that "Arthrex makes the unsupported argument that the first fiber-forming materials are just for 'pliability.'" DePuy Mitek Resp. at 7. Defendants, however, *never* told the Court that improved pliability was the only function of the first set of yarns. Rather, defendants asserted -- correctly -- that the specification teaches that the first set of yarn

are included to improve pliability, that this teaching is emphasized throughout the specification, and that UHMWPE would not fit in this description because it is stiff, not pliable. Def. Open. Br. at 11.[5] DePuy Mitek *never* disputes that the patent teaches that the first set of yarns (of which "PE" is one) are pliable and it *never* disputes that UHMWPE is not pliable.[6]

DePuy Mitek's contention that Arthrex ignores "the totality of the specification, which has much broader teachings" (DePuy Mitek Resp. at 7) is meritless. The first two bullet points relate to the broad, abandoned claims that required only that there be two dissimilar materials. The third bullet point is the one that defendants do rely upon.[7]

Finally, DePuy Mitek's argument that UHMWPE meets the requirement of the first set of yarns and PET meets the criteria of the second set of yarns (DePuy Mitek Resp. at 8-10) bears no relationship to the teachings of the patent. As we have shown above (and in several other submissions), UHMWPE decidedly does not meet the description of the first set of yarns, which describes a highly pliable, lubricious material that needs to be balanced with a stronger material

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[5] General purpose PE, unlike UHMWPE, is a very pliable substance. Ex. 1 at ¶¶ 4-5, and Exhibits B and C, thereto (comparing the pliability of a general purpose PE to UHMWPE). General purpose PE fits perfectly with the description of the first set of yarns in the '446 patent; UHMWPE does not.

[6] DePuy Mitek argues that Dr. Brookstein "*did not* acknowledge that ultra high molecular weight PE is stiff and not pliable," but only acknowledged that defendants' witness testified that that Arthrex believed that the original prototype of an all UHMWPE braid was too stiff. DePuy Mitek Resp. at 9 n.6. DePuy Mitek conveniently ignores Dr. Brookstein's testimony that UHMWPE "can have very poor pliability." Ex. 3 at 299:1-3.

[7] DePuy Mitek contends that defendants ignore the "compliance" and "surface lubricity" functions of the first set of yarns and asserts that the UHMWPE in FiberWire improves "compliance" and "surface lubricity." This argument is not relevant and is plainly designed to cast attention away from the fact that UHMWPE is not pliable, the most important function of the first set of yarns. Moreover, DePuy Mitek does not offer a shred of evidence that UHMWPE serves the "compliance" or "surface lubricity" function. The patent never describes what is meant by "compliance," and the word in never used except in the sentence describing the purpose of the first set of yarns identified in the claims. Ex. 2, col. 4, ll. 11-14. But from the structure of that sentence, it appears that "compliance" is just being used as a synonym for pliable. UHMWPE, of course, is stiff, not pliable. As for surface lubricity, DePuy Mitek offers no evidence that UHMWPE is added to FiberWire to improve surface lubricity.

because it is too weak. DePuy Mitek cannot wish away the fact that UHMWPE is strong and *not* pliable by limiting its discussion to "lubricity."

DePuy Mitek's assertion that PET, as used in FiberWire, is a "strong" material within the meaning of the '446 patent is yet another example of DePuy Mitek's effort to twist the '446 patent into something it is not. DePuy Mitek does not bother to explain what it means when it describes PET as strong. But in its Opposition to Defendants' Motion for Summary Judgment, it does explain its reasoning. Relying on Dr. Brookstein, DePuy Mitek claims that PET imparts what Dr. Brookstein calls "knot holding strength to the heterogeneous braid" DePuy Mitek Opp. at 7. Dr. Brookstein, however, simply makes up the word "knot holding strength" to describe what is the well-known property of knot security. While DePuy Mitek blithely asserts that "[k]not holding strength is a recognized suture strength property," its sole support for that statement is Dr. Brookstein's declaration where he *cited absolutely nothing* for this made up term. Ex. 4 at ¶20. Moreover, DePuy Mitek mischaracterizes Mr. Grafton's testimony. While Mr. Grafton explained, over and over again, that a purpose of adding PET was to improve the knot security of the braid (Ex. 5 at 53:8-19, 53:24-54:5)**,** he was not testifying that PET was added to improve the strength of the braid. In fact, he said exactly the opposite. Mr. Grafton testified that the strength of the braid, without PET, was excellent**.** Ex. 5 at 45:16-46:9.

DePuy Mitek's attempt to twist knot security into a "strength" criteria has nothing to do with strength, as that term is used in the '446 patent to describe the second set of yarns. That description is speaking of tensile strength, going so far as to describe the specific amount of yarn tenacity that is desired. Ex. 2 at col. 4, ll. 33-40**.** The patent could not be clearer that "strength" is used to describe the tensile properties, that is "straight and knot tensile strength." *Id*. at col. 6, ll. 32-36, Table at col. 7-8. By contrast, the patent does *not* use the word strength to describe

knot security (*id*. at col. 6, ll. 36-44, Table at col. 7-8), a fact that Dr. Brookstein was reluctantly forced to admit. Ex. 3 at 374:2-15.[8]

Finally, DePuy Mitek's argument about the prosecution history misses the point. As we have previously pointed out, the purpose of considering the prosecution history is not just to see if a disclaimer was made, but rather to help understand how the PTO and the inventor understood the patent. Def. Claim Opp. at 17. Likewise, all the spin in the world cannot change the fact, as we demonstrated before, that Ethicon told the PTO that the Burgess braid (UHMWPE and polyester or nylon) would make a poor suture because it contained UHMWPE.

Dated: September 15, 2006

Respectfully submitted,

By:/s/Charles W. Saber

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[8] DePuy Mitek's argument that the patent does not suggest that the first set of yarns be "relatively weak" in relation to the second set of yarns is contradicted by the patent. Why else would the patent teach that the first set of yarns needs to be combined with a stronger yarn? Ex. 2 at col. 4, ll. 9-40. Likewise, DePuy Mitek's reference to "polypropylene" simply has no relevance; the issue is the meaning of "PE," not polypropylene. Moreover, contrary to DePuy Mitek's implication, Dr. Mukherjee never testified that "ultra high weight polypropylene" (even if it exists in fiber form) would be encompassed by the term "PP" in the '446 patent. He simply was never asked any such question. Ex. 6 at 297:9-13.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Reply in Support of Their Opening Brief on Claim Construction was served, via the Court's email notification system on the following counsel for Plaintiff on the 15th day of September 2006:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc., *et al.* a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DECLARATION OF DR. DEBI PRASAD MUKHERJEE

1. My name is Dr. Debi Prasad Mukherjee. I am an Associate Professor and the Coordinator of Bioengineering in the Department of Orthopaedic Surgery at the Louisiana State University Health Sciences Center, in Shreveport, Louisiana. My CV is attached as Ex. A.

2. I am the same Dr. Debi Prasad Mukherjee who prepared the "Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446" dated March 3, 2006, the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters" dated March 24, 2006, and the "Rebuttal Expert Report of Dr. Debi Prasad Mukherjee" dated April 13, 2006.

3. I have been asked to provide my opinion regarding the relative stiffness and the relative tensile strength of ultra high molecular weight polyethylene (UHMWPE) fiber and general purpose polyethylene fiber.

4. It is my opinion that UHMWPE fiber is greater than approximately 100 times more stiff than the general purpose polyethylene fiber to which it is being compared. That is, the general

purpose polyethylene fiber is greater than approximately 100 times more pliable than UHMWPE fiber.

5. My opinion regarding the relative stiffness of UHMWPE fiber and general purpose polyethylene fiber is based on the fact that UHMWPE fiber has a tensile modulus on the order of 117GPa (Giga-Pascals) (Ex. B at 5-26), whereas general purpose polyethylene fiber has a tensile modulus on the order of 0.849GPa. Ex. C at Figure 12 (HMW HDPE). The higher a fiber's tensile modulus, the more stiff the fiber. Accordingly, the general purpose polyethylene would be considered a pliable substance when used with suture and UHMWPE would be considered a stiff material when applied to suture.

6. It is also my opinion that UHMWPE fiber is greater than approximately 60 times stronger than the general purpose polyethylene fiber. That is, the general purpose polyethylene fiber is greater than approximately 60 times weaker than UHMWPE fiber.

7. My opinion regarding the relative strength of UHMWPE fiber and the general purpose polyethylene fiber is based on the fact that UHMWPE fiber has a tensile strength on the order of 2590MPa (Mega-Pascals) (Ex. B at 5-26), whereas the general purpose polyethylene fiber has a tensile strength on the order of 40MPa. Ex. C at Figure 11 (HMW HDPE).

8. It is my opinion that UHMWPE is one of the strongest synthetic fibers ever created. Ex. B at 5-26.

9. It is also my opinion that general purpose polyethylene has been used in industry for decades and has established itself as a general purpose commodity polymer.

10. Since its introduction in fiber form in the 1980s, UHMWPE, has been considered a specialized high performance product. Ex. B at 5-26.

11. The key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. D at 4.

12. UHMWPE has a molecular weight of up to approximately 6 million, whereas general purpose PE has a molecular weight of up to approximately 200,000. Ex. D at 4.

13. UHMWPE also exhibits a much higher degree of crystalline orientation as compared with general purpose PE. These differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. D at 4, 6.

14. It is well known in the surgical suture art that a suture must be sterilized before it can be used in any surgical application.

15. FDA Publication "510K Sterility Review Guidance K90-1; Guidance for Industry and FDA" governs the sterilization of medical devices, including surgical suture. Ex. E.

16. It is my opinion that a person of ordinary skill in the surgical suture art would understand that the suture disclosed in U.S. Patent No. 5,318,575 must be sterilized before it can be used in a surgical application.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed on: Sept 15, 2006

Debi Prasad Mukherjee

Dr. Debi Prasad Mukherjee

EXHIBIT A

CURRICULUM VITAE

Name

Debi Prasad Mukherjee, Sc.D.

Title

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Date of Birth

October 26, 1939

Family

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Sons: Avik
Shomik

Education

1961 B.Ch.E. (Hons), Chemical Engineering, Jadavpur University
1965 S.M., Biochemical Engineering, M.I.T.
1965 S.M., Chemical Engineering, M.I.T.
1967 Ch.E., Chemical Engineering, M.I.T.
1969 Sc.D., Chemical Engineering, M.I.T.
1980 M.B.A., Business Administration, University of Connecticut

Employment History

1992-Present Associate Professor and Coordinator of Bioengineering
Louisiana State University Health Sciences Center, Shreveport, Louisiana

1991-1992 Development Scientist
Union Carbide, Bound Brook, New Jersey

1987 - 1990 Research Program Manager
Dow Corning Wright, Arlington, Tennessee

1974 - 1987 Technical Specialist, Biomaterials
Group Leader, Extrusion & Materials Development
Senior Research Engineer

Davis & Geck, American Cyanamid Company, Danbury, Connecticut

1969 - 1974 Senior Research Engineer
The Goodyear Tire & Rubber Company, Akron, Ohio

Academic Appointment

1989 - 1993 Adjunct Associate Professor, Biomedical Engineering
Memphis State University, Memphis, Tennessee

1992 - Present Adjunct Associate Professor, Biomedical Engineering
Louisiana Tech, Ruston, LA.

Thesis Supervised

1. M.S. Thesis (1992) by J. D. Ray Jr. "A Comparison of Fatigue Behavior for APC-2/AS4 and Comningled PEEK/AS-4 Composite", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

2. M.S. Thesis (1992) by R. R. Shults, "A Characterization Study of Hydroxylapatite Coatings on Titanium Alloy Implant Material Before and After Fatigue", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

3. M.S. Thesis (1993) by H. A. Mansour, "Bone/Prosthesis Relative Rigidity as an Important Parameter in the Isoelasticity of Total Hip Arthroplasty of the Human Proximal Femur", Department of Biomedical Engineering, Memphis State University, Memphis, TN.

4. M.S. Thesis (1994) by P. R. Menon, "Composites of Hydroxylapatite with Water Soluble or Biodegradable Polymers as a Synthetic Bone Graft Material", Louisiana Tech University, Ruston, LA.

5. M.S. Thesis (1996), by S. Ashroff, "Effect of Crystallinity of Hydroxyapatite Coating on Titanium Implants After Cyclic Fatigue Loading", Louisiana Tech University, Ruston, LA.

6. M.S. Thesis (1996), by N.R. Dorairaj, "Effects of Cyclic Fatigue Loading on the Stability of Hydroxyapatite Coated Titanium Dental Implants in the Presence of the Periodontal Pathogens", Louisiana Tech University, Ruston, LA.

7. M.S. Thesis (1999) by J.R.Hunter, "The measurement of Stress shielding and Relative Rigidity Mismatch within the femur prosthesis union of Total Hip Replacement" Louisiana Tech University, Ruston, LA.

8. Ph.D. Thesis (2001) by Kelly Crittenden, "Evaluation of 135- and 150-degree

Sliding hip screws". Louisiana Tech University, Ruston, LA.

Honors and Awards

1. MNC Memorial Medal for securing the highest grade in the Sophomore Class of the Chemical Engineering Department, 1958.

2. E.F Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A study of burst fracture in a canine model, Louisiana Orthopaedic Association, Harry Morris Award, 1993.

3. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: "Comparison of Fixation of Locking Head and Conventional Screws in Fracture and Reconstruction Models." Winner of American College of Oral and Maxillofacial Surgeons Resident Research Award 18th Annual Meeting, San Diego, CA.,1997.

4. JW Sikes, BR Smith, and DP Mukherjee: "Effect of Bony Buttressing in the Atrophic Edentulous Mandible: An In Vitro Study." Winner of ITI Straumann Research Award, AAOMS 80th Annual Meeting, September 1998.

5. R Bhati, DP Mukherjee, KJ McCarthy, S Rogers, and DF Smith: "The Effect of Fibronectin Coating on the growth of Chondrocytes into a Biodegradable Scaffold." National Student Research Forum- The University of Texas Medical Branch of Galveston Texas, Department of Orthopaedic and Rehabilitation Award, 2000.

Editorial Board

Journal of Long Term Effect of Medical Implants
(Member of Editorial Advisory Board) 1998- Present

Journal of Biomedical Materials Research (Applied Biomaterials)
(Member of Editorial Board) 1998-2002.

Conferences Organized

Akron Polymer Lecture Group

Secretary, 1972
Program Chairman, 1973

14th Southern Biomedical Engineering Conference

Chairman
April 7-9, 1995, Shreveport, LA

Technical Sessions Chaired

Biomaterials:

11th Southern Biomedical Engineering, Memphis, TN (1992), Session Chairman

Determination of Bone Properties:

12th Southern Biomedical Engineering, New Orleans, LA (1993), Session Chairman

Biomechanics and Biomedical Engineering Symposium

Orthopaedics Biomechanics I: 31st Annual Technical Meeting of the Society of Engineering Science, Texas A&M (1994) Session Co-Chairman

Orthopaedic Biomechanics

13th Southern Biomedical Engineering, Washington, D.C. (1994)- Session Chairman

Dental Materials: natural dentition polymers and composites

Sixth World Biomaterials Congress, Hawaii (2000) Session Co-moderator

Polymers in Orthopaedics Symposium (American Chemical Society) August 2002

Chaired the session

Public/Community Service Activities

NIH Proposal Evaluations and Site Visits:

1. Reviewed the contracts on the biocrodible drug-delivery systems and was invited to a site visit to SRI on May 5-7, 1987, by the Contraceptive Development Branch, Center for Population Research, National Institutes of Health and Human Development - NIH contract, Dr. Dinesh Sharma.
2. Reviewed a number of proposal on drug-delivery systems and was invited for a working group in Bethesda, Maryland, on April 27, 1990, NIH contacts, Dr. H. Khan and Dr. D. Sharma.

3. Reviewed proposals on "Development and Testing of New Spermicides for National Institute of Child Health and Development", Bethesda, MD. June 16-17, 1992, NIH contact, Dr. S. Strenfert.
4. Special Study Section - Small Business Innovation Research (SBIR) Program, Rockville, MD, July 6-8, 1994, NIH contact, Dr. N. Vydelingum.
5. Task Group Chair, Scaffold Biomaterials Section, American Society of Testing and Materials (ASTM) 1998- 2001

Institute Activities

1992 - Present	Mentor ;Minority High School Student Research Apprentice Program
1992 - Present	Mentor: Summer Medical Student Research Program
1994 - 1995	Member of the Medical Communication Committee
1998-at present	Mentor: Science Medicine Academic Research Training Program
2001- Present	Flag Group Leader: Module III-New curriculum of instructions to Freshman/Sophomore Medical Students
2003-Present	Member of Institutional Review Board

Invited Lecturer:

Baylor College of Medicine, Department of Orthopaedic Surgery, -Grand Round – Plaster of Paris as a vehicle for delivery of tobramycin to treat Osteomyelitis, March, 13, 1994

Biomaterials Seminar in Atlanta: Technomic Publishing Co. Inc.
Tissue Engineering Applications of Bioabsorbable Polymers, November 16, 1999

Baylor College of Medicine, Department of Orthopaedic Surgery, - Grand Round Baylor University Medical center, Houston, TX, Meniscal Repair, May 7, 2003

Society Membership

Orthopaedic Research Society
Society for Biomaterials
American Association of Advancement of Science

Research Support and Meeting Grants

1. American Heart Association, Akron Chapter, December 10, 1973, for the project, The Relationship of Dynamic Mechanical Properties of Arteriosclerotic Tissue to the Deposit of Cholesterol and Its Ester, jointly with Dr. Thomas Pynadath of Kent State University, Kent, Ohio 44242, $8030.00

2. School of Dentistry, LSU Medical Center, and New Orleans. "Biomechanical In Vitro testing of the stability of HA coating etc.", jointly with Dr. J. Wittenberg, Department of Surgery, Division of Oral and Maxillofacial Surgery LSUMC-S, 1993, $7500.00.

3. ExacTech Inc., Gainesville, FL. "Experimental testing of components comprising the ExacTech 913 Knee System." 1993, $150.00

4. Whitaker Foundation: Fourteenth Southern Biomedical Engineering Conference, 1994, $6,000.00.

5. Smith & Nephew Richards: Fourteenth Southern Biomedical Engineering Conference, 1994, $1,000.00.

6. Sofamor Danek Medical: Fourteenth Southern Biomedical Engineering Conference, 1994, $300.00.

7. Dean - LSU School of Medicine-Shreveport: Fourteenth Southern Biomedical Engineering Conference, 1994, $4,500.00.

8. Center of Excellence for Arthritis & Rheumatology: 1992-1994, $37,070.00

9. Ortho-Care, Inc: 1994, $550.00.

10. Chitogenics, Inc.: Nov. 1995-May 1996, Evaluation of the carboxymethyl chitosan (NOCC) and hydroxyapatite composite paste for repairing bone defects in a rat model. Feasibility of using NOCC to complex with the hyaluronic acid to reduce the drop of viscosity of synovial fluids of the rheumatoid patients. $10,000.00.

11. Intramural Grant: January 1, 1997 - December 31, 1997. Tissue Engineering - Development of Scaffolds seeded with Different Cell types on a biodegradable matrix. $5,000.00.

12. Wright Medical Technology: June 15, 1997 - Feb. 1999. Measurement of Creep Properties of Bone Cement. $15,000.00

13. Louisiana Board of Regents: Travel Grant for Emerging Faculty. $500.00.

14. Celanese Acetate: November, 15, 1998- November 15, 1999. Feasibility study of modification of cellulose acetate filters (CAF) by gamma and electron beam radiations. $7,060.00.

15. Board of Regents Support fund, June 2000-June 2001 with matching grant from LSUHSC: Replacement of Biaxial Testing machine (Instron Model 1321) by a new digital biaxial machine (Model 8874): **$117,732.**

16. Clinical and Industrial technology Company, July 2000- July 2001: A New Vibration Mixer for Bone Cement: **$14,000.**

17. Department of Obstetrics & Gynecology , 2002-2003: "Biomechanical Studies on several Sutures". **$3420.**

18. W.L.Gore and Associates, Biodegradable Scaffold for Tissue Engineering , Jan -May 2004, **$5000.**

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EXHIBIT B

(1)

Engineers' Guide to Composite Materials

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This book is a collective effort involving a large number of technical specialists. It brings together a wealth of information from world-wide sources to help scientists, engineers, and technicians solve current and long-range problems.

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Comments, criticisms, and suggestions are invited, and should be forwarded to the American Society for Metals, Metals Park, Ohio 44073.

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Mechanical Properties of Aramid, Polyamide, Polyester, and Nylon Fibers

Fiber	Density Mg/m³	Density lb/in.³	Tensile strength MPa	Tensile strength ksi	Tensile modulus GPa	Tensile modulus 10^6 psi	Ultimate elongation, %
Aramid-Kevlar 29	1.44	0.052	3620	525	83	12	4.4
Aramid-Kevlar 49	1.44	0.052	3620	525	124	18	2.9
Polyamide	1.13	0.041	830	120	2.8	0.4	...
Polyester-Dacron Type 68	1.38	0.050	1120	162	4.1	0.6	14.5
Nylon–Du Pont 728*	1.13	0.041	990	143	5.5	0.8	18.3
Spectra-900	0.97	0.035	2590	375	117	17	...

*Unimpregnated twisted yarn test–ASTM D2250.

Effect of Tension-Tension Fatigue on Aramid (Kevlar 29) Fibers (Du Pont Co.)

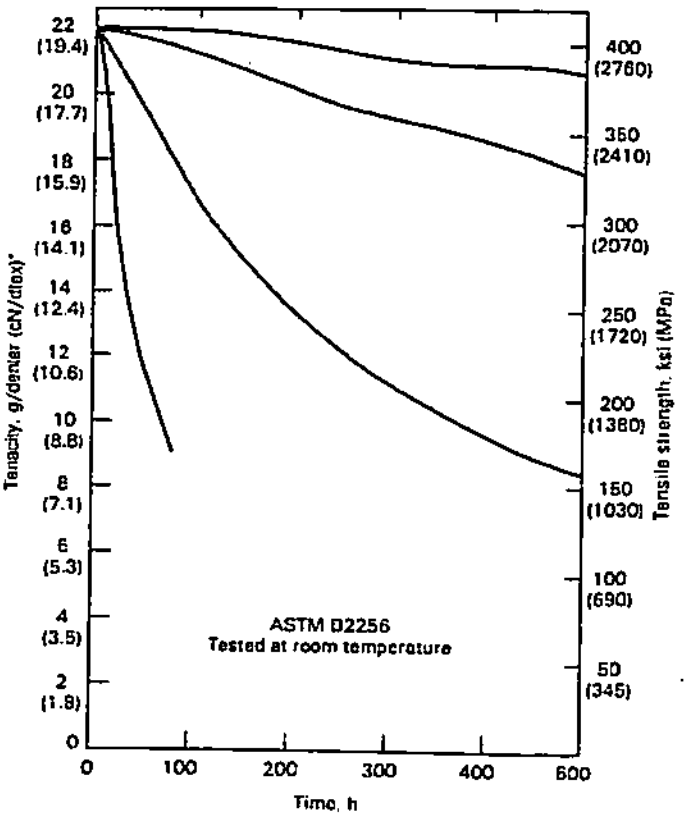
Cycled between (% of ultimate tensile strength) High	Low	No. of cycles	Break load after cycling N	Break load after cycling lb	Decrease in tensile strength due to fatigue
Control		...	552	124	...
74	45	1000	578	130	None
52	29	1000	610	137	None
31	8	1000	587	132	None
10	0	13×10^6	525	118	5%

1500 denier [1670 dtex] 2-ply yarn of Kevlar 29 was tested using air-actuated 4-D cord clamps on an Instron test machine, at 254 mm (10 in.) original gage length, 10% per minute elongation, 55% R.H., and 22 °C (72 °F).

Coating Materials Used Successfully With Kevlar 29 Aramid Fiber (Du Pont)

Coating	Typical end uses
Neoprene synthetic rubber	Inflatable boats
Hypalon synthetic rubber	Pond liners, tarpaulins
Nitrile rubber	Pressure diaphragms
Nordel hydrocarbon rubber	Heat-resistant conveyor belts
Buna-N	Hoses
Urethane polymers	Inflatable structures
Silicon and fluorosilicon	Belting
Polyvinyl chloride	Air-supported structures
Teflon [TFE, FEP] fluorocarbon resin	Nonstick belts
Polyvinyl alcohol	Specialty uses
Laminations: Tedlar polyvinyl fluoride / Mylar polyester	Lighter-than-air craft

Effect of Temperature on Tensile Strength of Aramid (Kevlar 29) Fiber (Du Pont Co.)



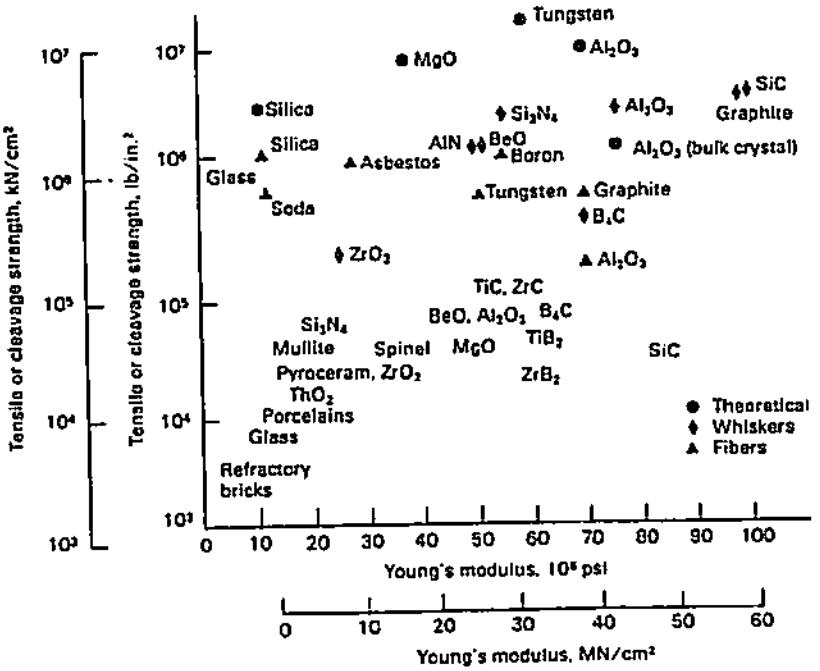
*Conversion factor: $\frac{\text{lb}}{\text{in}^2} = \left(\frac{\text{g}}{\text{denier}}\right) \times \text{density}\left(\frac{\text{g}}{\text{cm}^3}\right) \times 12\,800$

Chemical Resistance of Kevlar (Ref 34)

Chemical	Concentration, %	Temperature °C	Temperature °F	Time, h	Strength loss, % Kevlar 29	Strength loss, % Kevlar 49
Hydrochloric acid	37	21	70	100	72	63
Hydrochloric acid	37	21	70	1000	88	81
Hydrofluoric acid	10	21	70	100	10	6
Nitric acid	1	21	70	100	16	5
Nitric acid	10	21	70	100	79	77
Sulfuric acid	10	21	70	100	9	12
Sulfuric acid	10	21	70	1000	59	31
Sodium hydroxide	10	21	70	1000	74	53
Ammonium hydroxide	28	21	70	1000	9	7
Acetone	100	21	70	1000	3	1

(continued)

Strength Vs. Modulus for Tungsten and Various Ceramics in Bulk, Fiber, and Whisker Forms (Ref 8, p 359)

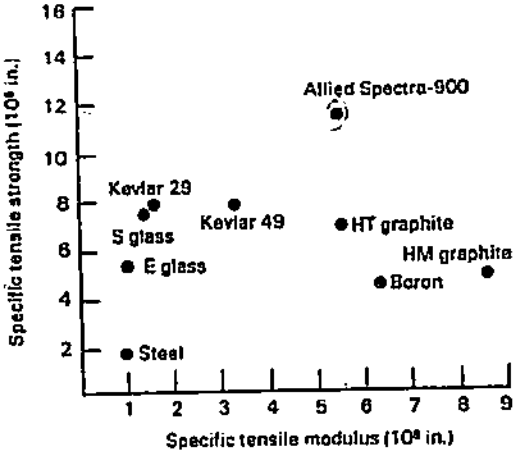


Comparative Mechanical Properties of Kevlar, Glass, and Graphite Fibers (Du Pont Co.)

Property	Kevlar 29	E glass	Graphite
Tensile strength*:			
MPa	3620	3415	2760
ksi	525	350	400
Tensile modulus*:			
GPa	82.7	68.9	220
10^6 psi	12	10	32
Density:			
g/cm³	1.44	2.52	1.74
lb/in.³	0.052	0.091	0.063
Brittleness	Tough	Brittle	Brittle
Abrasiveness	No	Yes	Yes

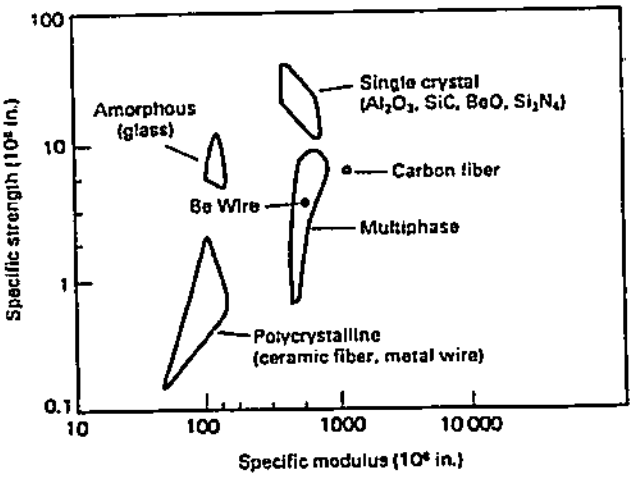
*Resin-impregnated strand test.

Specific Strength Vs. Specific Modulus for Reinforcing Fibers (Allied Fibers)



Room-Temperature Specific Strength and Specific Stiffness of Several Fibers (Ref 11, p 25)

Specific values in this figure were determined by dividing strength or modulus by density, expressed in lb/in.³ or kg/M³.



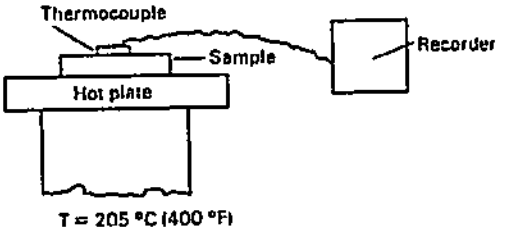
Characteristics of Carbon-Boron Alloy Fiber Groups (Ref 73)

Characteristic	Group A	Group B	Group C	Group D
Carbon interlayer	No	No	Yes	Yes
Number of CVD reaction chambers	4	3	3	3
Boron content*, wt %	43–46	35–39	46–48	48–51

*Unpublished research, D. L. McDanels, NASA Lewis Research Center.

Thermal Conductivity of Kevlar Felts and Fabrics Vs. Other Materials (Du Pont Co.)

Fabric	Weight g/m²	Weight oz/yd²	Thickness mm	Thickness mils	Lag time, s	Thermal conductivity, cal/cm²·s·°C	Temperature rise in 25 s °C	Temperature rise in 25 s °F
Kevlar 29 (1 ply)	333	9.8	0.76	30	0	0.324	60	108
Kevlar 29 (3 ply)	998	29.4	2.16	85	3	0.162	30	54
Kevlar 29 (felt)	917	27.0	2.67	105	1.5	0.084	16	28
Fiberglass (1 ply)	285	8.4	0.30	12	0	0.600	111	200
Fiberglass (8 ply)	2282	67.2	2.16	85	5.1	0.105	19	35
Asbestos	1386	40.8	2.29	90	2.5	0.168	31	55



Schematic of Test Apparatus for Determining Lag Time

Lag time is time between placing sample in contact with hot plate and any perceptible recorder readout.

Some Typical Fabric Dimensions (Hexcel-Trevarno)

Construction	Weave	Thickness, mils	Width, in.	Weight, oz/yd²
Graphite				
12.5 × 12.5	Plain	7.2	42	5.7
24.0 × 24.0	Satin	13.5	42	10.0
10.5 × 10.5	Plain	6.0	42	5.5
10.0 × 24.0	Plain	6.1	38	4.7
Kevlar				
34 × 34	Plain	4.5	38	1.8
50 × 50	Satin	11	38	5.0
22 × 22	Plain	4.5	38	2.2
17 × 17	Plain	10	38, 50	5.0
17 × 17	Crowfoot	10	38, 50	5.0
13 × 13	Plain	10	50	5.0
16 × 16	Satin	13	50	9.0
28 × 28	Basket	20	50	10.5
26 × 22	Basket	20	44, 50, 60	13.5
17 × 30	Plain	7	38	3.1
S Glass				
24 × 22	Plain	5.5	38	3.7
18 × 18	Plain	9	38	5.8
48 × 30	Crowfoot	9	30	8.8
57 × 30	Crowfoot	5.5	38	5.4
57 × 54	Satin	8.5	38	8.9
Ceramic				
48 × 47	Satin	9.0	38	7.5

Comparative Textile Fiber Properties (Ref 90)

	Spectra 900	Spectra 1000	Aramid LM	Aramid HM	Carbon HT	Carbon HM
Denier/Number of filaments	1200/118	650/120	1500/1000	1500/1000	1730/3000	1630/3000
Tenacity, g/d	30	35	22	22	20	14
Elongation, %	3.5	2.7	3.6	2.8	1.2	0.6
Tensile modulus, g/d	1400	2000	488	976	1500	2400
Shrinkage at boil, %	<1	<1				
Specific gravity	0.97	0.97	1.44	1.44	1.73	1.81
Melting point, °C	147	147				
Filament size, μm	38	27	12	12	7.0	6.5

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EXHIBIT C

JOURNAL OF APPLIED POLYMER SCIENCE VOL. 18, PP. 2539-2568 (1974)

Interaction of Melt Spinning and Drawing Variables on the Crystalline Morphology and Mechanical Properties of High-Density and Low-Density Polyethylene Fiber

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Synopsis

An experimental study of the spinnability and the variation in crystallinity and orientation in high-density and low-density polyethylene fibers with melt spinning and drawing conditions has been carried out. Three polymers (two high-density and one low-density) and eicosane ($C_{20}H_{42}$) were studied. The maximum spinnability was in the lower molecular weight high-density polyethylene. Hermans-Stein a, b, and c crystallographic axis orientation factors were computed from wide-angle x-ray scattering patterns. In the spun fiber, small take-up velocities cause the b axis to become perpendicular to the fiber axis in each fiber. The c axis increasingly orients itself parallel to the fiber axis as take-up velocity increases. The a axis orientation is different for each polymer. The results are interpreted in terms of modern theories of crystalline morphology, specifically the development of row structures. In the drawing experiments, the two high-density polyethylenes necked. A phenomenological theory of necking is discussed. The a, b, and c axis orientation factors were determined for different stages of drawing. In the necked regions and in completely drawn fibers, the c axis was parallel to the fiber axis and the a and b axes are perpendicular to the fiber axis. The tangent Young's modulus and tensile strength of the spun fibers increased with take-up velocity and in the drawn fibers were an order of magnitude higher than in the spun fiber. The mechanical properties of spun fiber may be correlated with the c axis (Hermans) orientation factor. The drawn fiber shows significant variations in Young's modulus and tensile strength at constant unit cell orientation.

INTRODUCTION

The production of fibers from polymer melts generally involves two steps. First, melt is extruded producing a vertical descending thread which is cooled in transit and taken up on a godet in solidified form. This process is known as *melt spinning*. The spun fiber is then subjected to a second operation in which it is unwound from a slow roll, stretched (drawn) under controlled temperature conditions, and taken up on a fast roll. This second process is known as *drawing*. A wide range of spinning and drawing variables is available to the fiber manufacturer. The choice is one not to be taken lightly or completely on the basis of economic considerations for the

D.F.M. 8/11/06

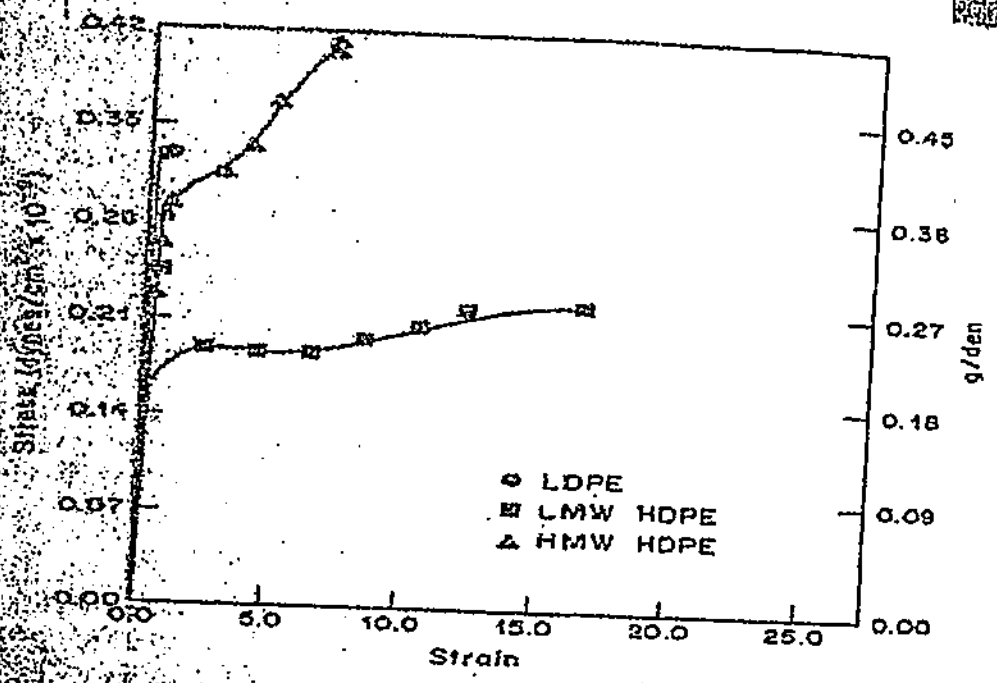
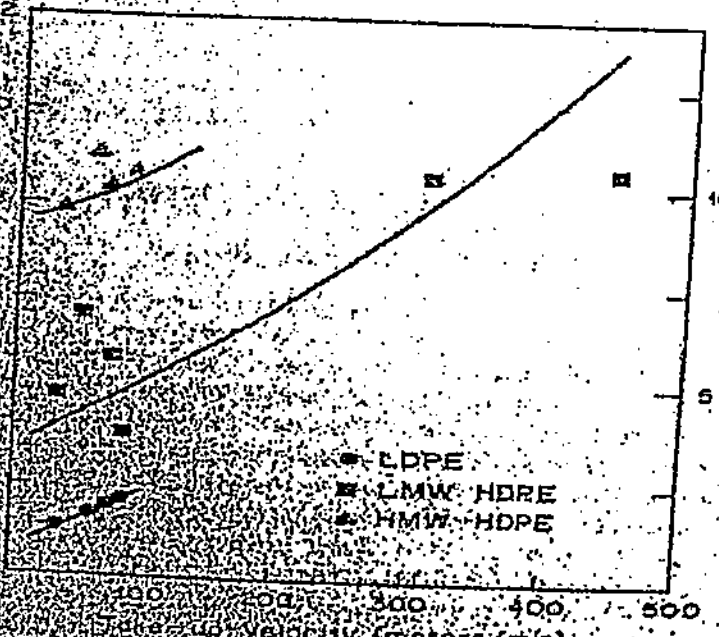


Fig. 11. Stress–strain curves for three different polyethylene fibers spun under the same conditions.



...polyethylene fibers as a function of take-up velocity.

DPM
8/11/06

EXHIBIT D

(2)

The UHMWPE Handbook

Ultra-High Molecular Weight Polyethylene in Total Joint Replacement

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the elemental building blocks are individual metal atoms (e.g., Co, Cr, Mo) or relatively small molecules (e.g., metal carbides or oxides). However, in a polymer, the molecular size can comprise more than a 100,000 monomer units, with molecular weights of up to millions of g/mol.

The molecular chain architecture of a polymer also imparts many unique attributes, including temperature dependence and rate dependence. Some of these unique properties are further illustrated in the specific case of UHMWPE in subsequent sections of this chapter. For further background on general polymer concepts, the reader is referred to textbooks by Rodriguez (1989) and Young (1983).

What Is Polyethylene?

Polyethylene is a polymer formed from ethylene (C_2H_4), which is a gas having a molecular weight of 28. The generic chemical formula for polyethylene is $-(C_2H_4)_n-$, where n is the degree of polymerization. A schematic of the chemical structures for ethylene and polyethylene is shown in Figure 1.4.

For UHMWPE, the molecular chain can consist of as many as 200,000 ethylene repeat units. Put another way, the molecular chain of UHMWPE contains up to 400,000 carbon atoms.

There are several kinds of polyethylene (LDPE, LLDPE, HDPE, UHMWPE), which are synthesized with different molecular weights and chain architectures. LDPE and LLDPE refer to low-density polyethylene and linear low-density polyethylene, respectively. These polyethylenes generally have branched and linear chain architectures, respectively, each with a molecular weight of typically less than 50,000 g/mol.

HDPE is a linear polymer with a molecular weight of up to 200,000 g/mol. UHMWPE, in comparison, has a viscosity average molecular weight of up to 6 million g/mol. In fact, the molecular weight is so ultra-high that it cannot be measured directly by conventional means and must instead be inferred by its intrinsic viscosity (IV).

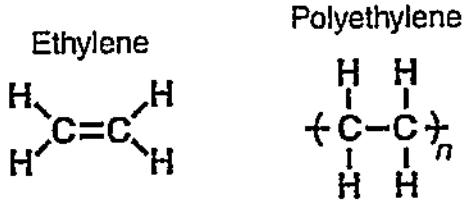

Figure 1.4
Schematic of the chemical structures of ethylene and polyethylene.

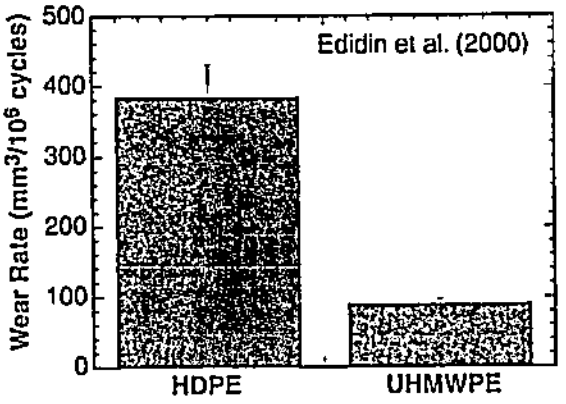

Figure 1.5
Comparison of wear rates of HDPE and UHMWPE in a multidirectional hip simulator. (From Edidin A.A., and S.M. Kurtz. 2000. The influence of mechanical behavior on the wear of four clinically relevant polymeric biomaterials in a hip simulator. *J Arthroplasty* 15:321–331.)

Crystallinity

One can visualize the molecular chain of UHMWPE as a tangled string of spaghetti, more than a kilometer long. Because the chain is not static, but imbued with internal (thermal) energy, the molecular chain can become mobile at elevated temperatures. When cooled below the melt temperature, the molecular chain of polyethylene has the tendency to rotate about the C–C bonds and create chain folds. This chain folding, in turn, enables the molecule to form local ordered, sheetlike regions known as crystalline lamellae. These lamellae are embedded within amorphous (disordered) regions and may communicate with surrounding lamellae by tie molecules. All of these morphological features of UHMWPE are shown schematically in Figure 1.6.

The degree and orientation of crystalline regions within a polyethylene depends on a variety of factors, including its molecular weight, processing conditions, and environmental conditions (such as loading), and will be discussed in later chapters.

The crystalline lamellae are microscopic and invisible to the naked eye. The lamellae diffract visible light, giving UHMWPE a white, opaque appearance at room temperature. At temperatures above the melt temperature of the lamellae, approximately 137°C, UHMWPE becomes translucent. The lamellae are on the order of 10–50 nm in thickness and 10–50 μm in length (Kurtz et al. 1999). The average spacing between lamellae is on the order of 50 nm (Bellare, Schnablegger, and Cohen 1995).

The crystalline morphology of UHMWPE can be visualized using transmission electron microscopy (TEM), which can magnify the polymer by up to

summarizes the clinical performance of UHMWPE hip implants and discusses the patterns of wear and surface damage that occur during implantation. Chapter 6 describes alternatives to conventional UHMWPE in hip replacement. Chapters 7 and 8 relate to the development and clinical performance of UHMWPE in knee replacement. Chapter 9 is devoted to clinical applications of UHMWPE in the shoulder, and Chapter 10 covers the use of UHMWPE in the spine.

The topics outlined in this *Handbook* may be used as a resource in undergraduate, as well as graduate, courses in biomaterials and orthopedic biomechanics. Students in these disciplines can learn a great deal from exposure to the historical development of total joint replacements within the context of UHMWPE. The first two main sections of this book, which cover the fundamentals of UHMWPE and clinical applications in the spine and upper and lower extremities, are intended as a resource for undergraduate instruction.

The third section of this book, which covers more specialized topics related to UHMWPE, is intended for an audience of graduate students and orthopedic researchers. Chapter 11 covers the chemistry of UHMWPE following irradiation, which leads to oxidation and crosslinking of the material. Chapter 12 describes the characterization methods for UHMWPE in the context of regulatory submissions prior to clinical trials. In Chapter 13, we review the development of the small punch test, a miniature specimen mechanical testing technique that has recently been standardized. Chapter 14 describes the micromechanical modeling of conventional and highly crosslinked UHMWPE. The final chapter in this work, Chapter 15, is a compendium of the processing, packaging, and sterilization information for highly crosslinked and thermally treated UHMWPE materials that are currently used in hip and knee arthroplasty.

Understanding basic chemical structure and morphology is an important starting point for appreciating the unique and outstanding properties of UHMWPE. The chapters that follow and describe the processing, as well as the sterilization, of UHMWPE will continue to build on the conceptual foundation established in this introduction.

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Chapter 1. Reading Comprehension Questions

1.1. Let A, B, and C be monomers. What is the molecular structure of a linear homopolymer?
- a) -A-A-B-A-A-B-A-A-B-
- b) -A-B-C-A-B-C-A-B-C-
- c) -B-C-C-C-C-C-C-C-C-
- d) -B-B-B-B-B-B-B-B-B-
- e) -C-A-A-C-A-A-C-A-A-

1.2. Which of the following polymers is NOT synthesized from ethylene?
- a) LLDPE
- b) PTFE
- c) UHMWPE
- d) HDPE
- e) LDPE

1.3. What is the major difference between HDPE from UHMWPE?
- a) Molecular weight
- b) Monomer
- c) Chemical composition
- d) Color
- e) All of the above

1.4. What are the crystals in polyethylene made up of?
- a) Folded molecular chains
- b) Calcium stearate
- c) Aluminum tetrachloride
- d) Copolymer
- e) Branched chain ends

1.5. UHMWPE exhibits which of the following transition temperatures?
- a) Glass transition
- b) Melting transition
- c) Flow transition
- d) Glass and melting transitions
- e) Glass, melting, and flow transitions

EXHIBIT E

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA

Document issued on: August 30, 2002

This document supersedes 510(k) Sterility Review Guidance K90-1, dated November 16, 2001.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Timothy A. Ulatowski at (301) 443-8879 or by email tau@cdrh.fda.gov.

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Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

On November 16, 2001, the Office of Device Evaluation released updated review procedures regarding sterilization data submitted in premarket notification (510(k)) submissions as outlined in Blue Book Memorandum #K90-1, issued on February 12, 1990. The issuance of the November memorandum was deemed necessary given several significant changes that had occurred in the regulatory environment that had made aspects of the February 1990 memorandum obsolete. Specifically, these included:

1. Promulgation of the Quality System regulation (QS regulation, 21 CFR 820) in 1996;

2. Issuance of Blue Book Memorandum #K97-1 regarding changes to existing devices that can be made without submitting a new 510(k); and

3. Enactment of the Food and Drug Administration (FDA) Modernization Act of 1997 (FDAMA), which among many things, separated compliance with QS requirements from the substantial equivalence decision in most cases.

In 1997, the Center for Devices and Radiological Health (CDRH) decided that, given a manufacturer's obligation to comply with the QS requirements, the safety and effectiveness of a device manufacturer's sterilization process would best be ensured through compliance with the QS regulation rather than through 510(k) review. This decision was communicated to ODE staff and the medical device industry in Blue Book Memorandum #K97-1 entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[1] In this guidance, CDRH stated that manufacturers may modify existing devices in a number of ways, including labeling changes, technology or performance specification changes, and materials changes without submitting a new

[1] This guidance is available on CDRH's website at: http://www.fda.gov/cdrh/ode/510kmod.html

510(k) unless 'a change or the sum of the incremental changes exceeds the section 807.81(a)(3) threshold, "could significantly affect the safety or effectiveness of the device.'" CDRH included changes in the sterilization method as a type of change that would not normally trip the regulatory threshold for submission of a new 510(k). As stated in the guidance, changes in sterilization processes do not require 510(k) clearance, unless the changes significantly alter the properties/specifications of a device or result in a lower sterility assurance level (SAL). In instances where a manufacturer concludes that a change in sterilization method has not significantly affected device properties/specifications or resulted in a lower SAL, no 510(k) need be submitted. Rather, the appropriate documentation must be maintained at the manufacturing site in accordance with the QS regulation requirements.

The enactment of FDAMA emphasized the separation between issues of compliance with the QS regulation and determinations of substantial equivalence (SE). In a new statutory provision, the agency was instructed not to withhold a determination of the initial classification of a device because of a failure to comply with any statutory provision unrelated to the SE decision unless "there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health." This new provision, Section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act, specifically includes noncompliance with good manufacturing practices (now referred to as QS requirements) as a failure that should not ordinarily delay an SE decision. These events prompted FDA to revise its procedures for the review of sterilization information in all 510(k) submissions in 1997 and to issue the November 2001 memorandum.

In recent discussions with Center staff, it was determined that additional guidance on non-traditional methods of sterilization is needed. While the agency has experience with some types of non-traditional methods of sterilization, FDA recognizes that there may be unique or novel sterilants that have not yet been submitted in a premarket notification or that have not yet been successfully implemented by device manufacturers. Given this variety in non-traditional methods, CDRH decided that additional guidance is needed to help review staff differentiate between various types of non-traditional methods of sterilization and how applications in which they are employed should be handled.

II. Methods of Sterilization

FDA considers there to be two categories of sterilization methods used to sterilize medical devices - traditional and non-traditional. Specific methods for each category are listed below.

A. Traditional Methods of Sterilization

Traditional methods of sterilization include:

- Dry heat sterilization
- Moist heat sterilization

- Ethylene Oxide (EO) with devices placed in a fixed chamber
- Radiation (gamma and electron beam)
- Liquid chemical sterilants for sterilizing single-use devices incorporating materials of animal origin

B. Non-Traditional Methods of Sterilization

In general, methods of sterilization outside the scope of specific CDRH-recognized standards are non-traditional. A new method of sterilization remains a non-traditional method unless and until: a) the specific sterilization method is incorporated into a new or existing voluntary consensus standard formally recognized by the Agency or b) CDRH evaluates the validation data for the method of sterilization as part of a quality system evaluation and finds it satisfactory for specified types of devices.

1. As of the date of this memorandum, non-traditional methods of sterilization include:

   - EO not using a fixed chamber, e.g., EO injection into a porous polymer bag. Terms used for this process include:

     - "bag method"
     - "diffusion method"
     - "sterilization pouch"
     - "injection method"
     - "validation parts 'A' and 'B'"

   Less common indications of this type of sterilization are:

     - a long gas dwell time (>8 hours) or the absence of a specified gas dwell time
     - use of EO volume (e.g., 7.2 grains) instead of concentration (e.g., 500 – 600 mg/l)
     - mention of EO (or gas) cartridge
     - use of humidichips
     - use of "100% EO in-house"

- High intensity light
- Chlorine dioxide
- Ultraviolet light
- Combined vapor and gas plasma
- Vapor systems (e.g., peroxide or peracetic acid)
- Filtration methods
- Limited use of a liquid peracetic acid system in endoscopy and with metal instruments

2. In addition to the above non-traditional sterilization methods, ODE reviewers are occasionally presented with non-traditional methods employing a unique or novel sterilant that the agency has not previously seen in a premarket submission, for which there is no related inspectional history, or for which there is little or no published literature discussing its safety and effectiveness for its intended use. Such methods include, but are not limited to, the use of microwave radiation, pulsed light, gas plasma, and sound waves. Given that the agency has had little or no experience with these methods for achieving sterilization and is concerned about a manufacturer's ability to successfully use such methods without adversely affecting the SAL, reviewers should follow the additional procedures identified below in Section IV when reviewing a 510(k) in which a sterilization method of this type is employed.

III. Review Procedures for All Sterilization Methods

Regardless of the method of sterilization, ODE scientific reviewers should gather and review the following sterilization information for all 510(k)s for devices labeled as sterile:

- The sterilization method that will be used (e.g., dry heat, moist heat,E O, radiation);
- A description of the method that will be used to validate the sterilization cycle, but not the validation data itself;
- A description of the packaging to maintain the device's sterility, not including package integrity testing data;
- If sterilization involves EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: the ethylene glycol

residual level was dropped from this updated guidance because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);

- If the product is labeled "pyrogen free," a description of the method used to make the determination, e.g., limulus amebocyte lysate (LAL);
- The SAL (e.g., 10^{-6} for all devices, except 10^{-3} for devices only contacting intact skin); and
- In the case of radiation sterilization, the radiation dose.

IV. Additional Procedures for 510(k)s Citing Non-Traditional Sterilization Methods

As delineated in Blue Book #K97-1, a manufacturer's change in the sterilization method for an existing device will generally not require the submission of a new 510(k). Similarly, a manufacturer's use of a non-traditional sterilization method should not ordinarily effect or delay a substantial equivalence determination. In assessing the impact of a sterilization method on a device, the manufacturer should ensure that the performance characteristics have not been compromised and that the SAL remains 10^{-6} (10^{-3}, as appropriate). For 510(k)s citing a non-traditional method of sterilization, scientific reviewers should notify their Branch Chief of the pending submission and proceed as described below. Situations involving non-traditional sterilization methods should be brought to the attention of the Assistant to the Director, Office of Compliance, following the procedures below, so it can be determined whether conducting an inspection of the sterilization facility is a priority.

In order to maintain consistency in our approach to non-traditional methods of sterilization, we recommend that review scientists:

1. Identify the section in the submission related to a potential non-traditional method of sterilization;
2. Refer a copy of the section to the Branch Chief, Infection Control Devices (INCB), Division of Dental, Infection Control and General Hospital Devices (DDIGD) for consideration; and

INCB will assess the above information related to the non-traditional sterilization method and provide feedback to the referring ODE division and to OC, as needed. If INCB determines that the method is actually a traditional method, rather than a non-traditional method, then INCB will advise the referring ODE division of this determination and no referral will be made to OC.

If, however, INCB determines that the sterilization method is a non-traditional method, INCB will advise the referring ODE division and direct the information to OC for appropriate action. OC will review the information provided and consult with INCB to decide if an inspection of the sterilization facility should be considered a priority in the postmarket period. For novel, non-traditional sterilization methods for which the Agency has had limited experience (i.e., those identified in Section II, B, 2 above), INCB, along with the ODE referring division director and the ODE Deputy Director for Science and Regulatory Policy, will work with OC management to decide if an inspection may be needed in the premarket period. Throughout all of the situations described above, INCB will provide technical consultation to ODE and OC on non-traditional sterilization methods, as each situation requires.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before a device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred by industry's attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, industry believes that there is a less burdensome way to address the issues, the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document should be followed. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

Exhibit 2

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] STERILIZED HETEROGENEOUS BRAIDS

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

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3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
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WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

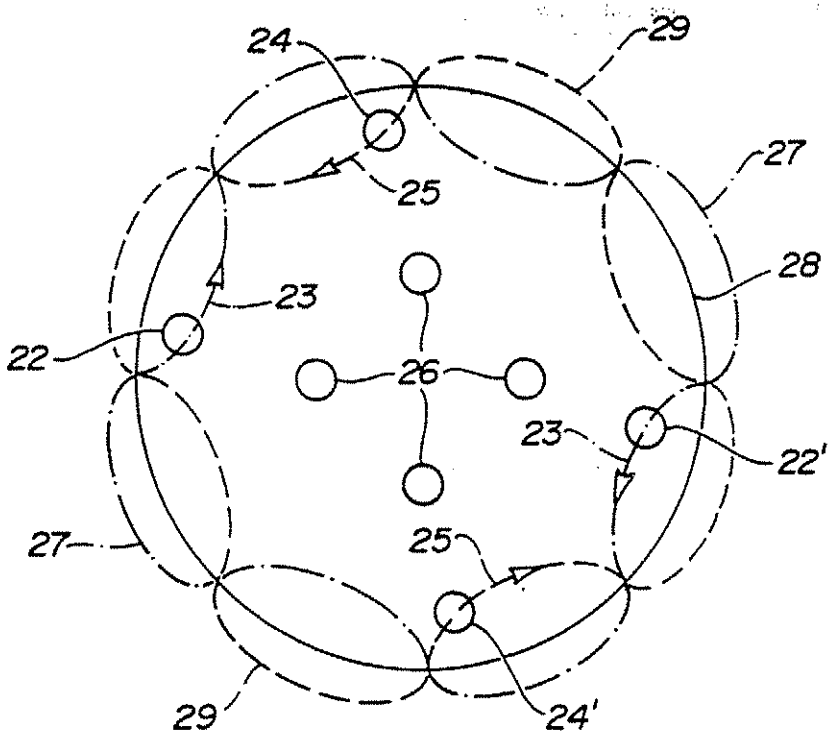
[57] ABSTRACT

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1



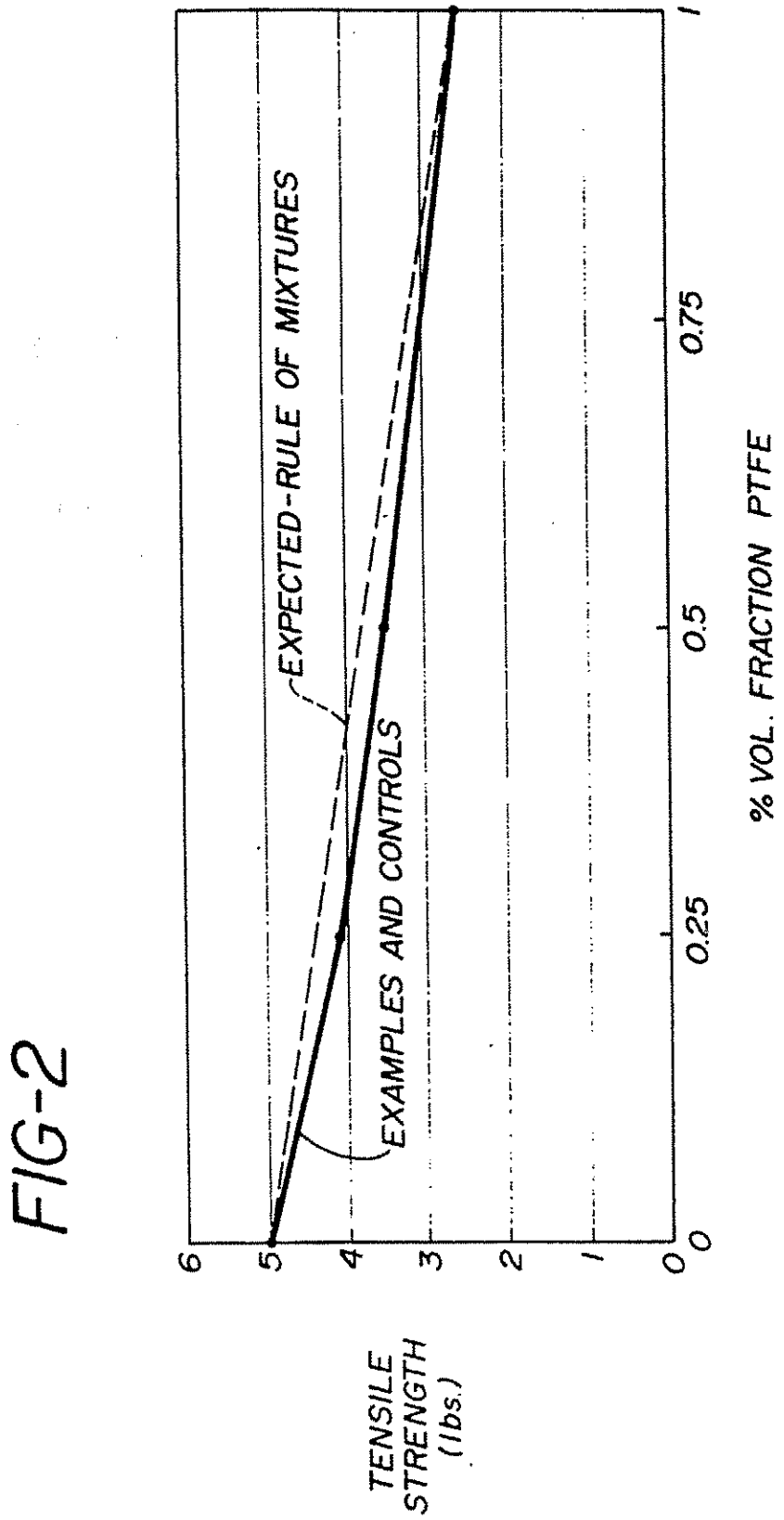
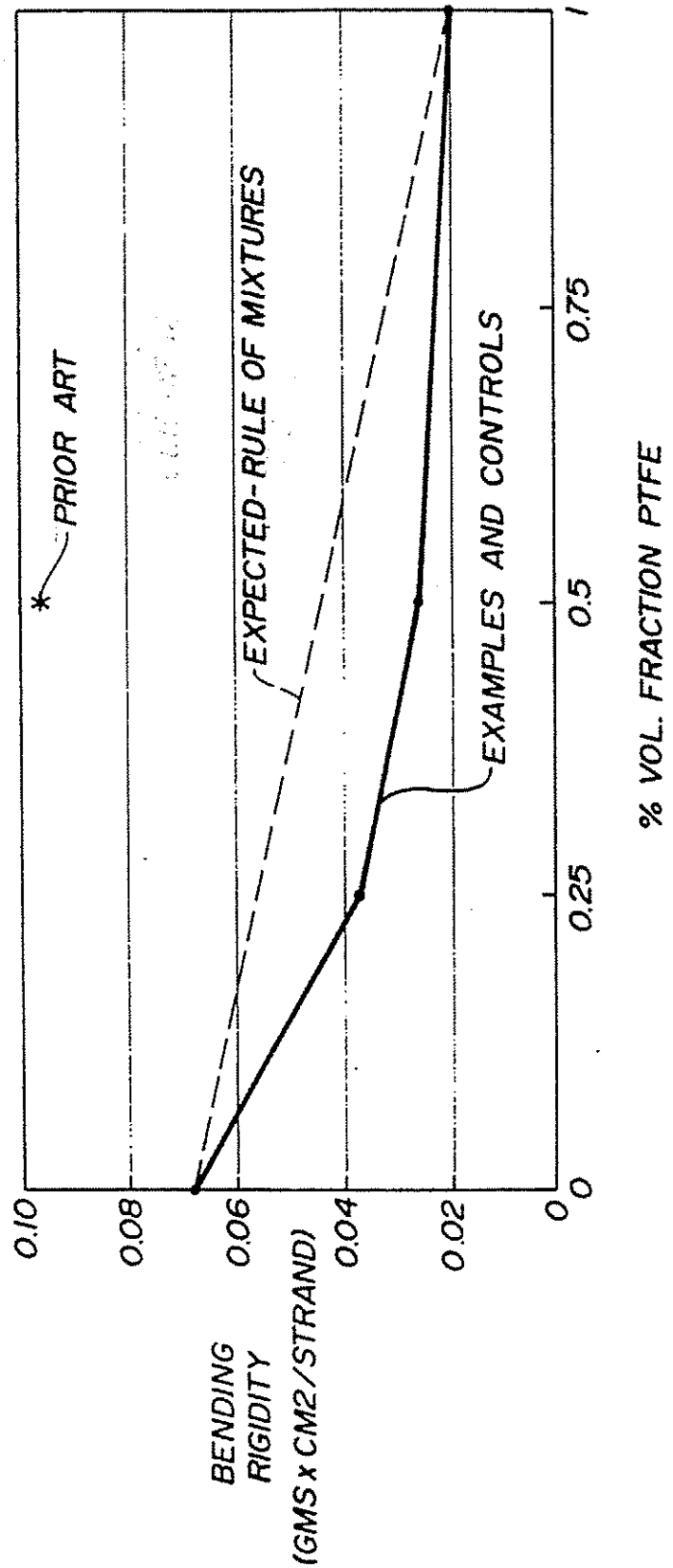

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
BENDING RIGIDITY (GMS x CM2/STRAND)
0.10
0.08
0.06
0.04
0.02
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogeneous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

Exhibit 3

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

DePUY-MITEK, INC.,
A Massachusetts Corporation,
Plaintiff,
vs.
ARTHREX, INC.,
A Delaware Corporation,
Defendants.

CONFIDENTIAL - OUTSIDE COUNSELS' EYES ONLY

DAY 1 OF 2

DEPOSITION OF DR. DAVID S. BROOKSTEIN

Philadelphia, Pennsylvania

July 26, 2006

Reported by:

PAMELA HARRISON, RMR, CRR, CSR

1	**Q. And does ultra high molecular weight**	**02:55:44p**
2	**have poor pliability?**	**02:55:49p**
3	A. It can have very poor pliability.	02:55:50p
4	**Q. And is it stiff, is it a stiff**	**02:55:52p**
5	**product?**	**02:55:54p**
6	A. In what dimension?	02:55:54p
7	**Q. I don't know. You write here that**	**02:55:56p**
8	**Arthrex had requested a less stiff braid.**	**02:55:59p**
9	A. Right.	02:56:03p
10	**Q. Does that mean that Arthrex felt -- at**	**02:56:04p**
11	**least is it your understanding that Arthrex felt**	**02:56:07p**
12	**that the ultra high molecular braid was too**	**02:56:10p**
13	**stiff?**	**02:56:12p**
14	A. I don't know if they were talking	02:56:12p
15	about tension or -- I don't know if they were	02:56:14p
16	talking about tension or bending. I don't know.	02:56:16p
17	**Q. You don't have an opinion as to --**	**02:56:19p**
18	A. No, I don't know. It's not an	02:56:20p
19	opinion. I don't know what they were talking	02:56:22p
20	about with tension or bending, what problem they	02:56:23p
21	were trying to resolve.	02:56:24p
22	**Q. When they said it's too stiff?**	**02:56:25p**
23	A. Right.	02:56:28p
24	**Q. But the PET was added to make it less**	**02:56:28p**
25	**stiff?**	**02:56:30p**

BY MR. SABER: 09:41:32a

Q. Do you see, sir, in the paragraph beginning in Line 21 -- Line 31, a discussion of knot security? 09:41:32a 09:41:34a 09:41:38a

A. Yes, I do. 09:41:41a

Q. It begins on Line 36? 09:41:41a

A. I see that. 09:41:44a

Q. Do you see in the discussion of knot security is there any use of the word strength? 09:41:45a 09:41:47a

A. There's the word breaking, breaking the strength. 09:41:56a 09:41:58a

Q. I asked you if the word strength is there. 09:41:58a 09:42:00a

A. I do not see the word strength in there. 09:42:00a 09:42:02a

Q. Now, when the knot -- could you look at the column -- the chart between Columns 7 and 9? 09:42:03a 09:42:16a 09:42:24a

A. Yes. 09:42:24a

Q. Does the '446 patent use the word strength to describe the knot stability test? 09:42:26a 09:42:30a

MR. BONELLA: Wait. Now you've taken him to a chart. Now you've just asked him whether the patent describes. Are you saying the patent or the chart? 09:42:33a 09:42:37a 09:42:40a 09:42:40a

Exhibit 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

Declaration of Dr. David Brookstein In Support of DePuy Mitek's
Claim Interpretation of the Hunter Patent and Summary Judgment of Infringement

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and conducted research in

polyester (Ex. 4 at 2:50-57). As the 234 patent explains, braiding polyester with UHMWPE improves knot tie down characteristics or the "ability to approximate the tissue and hold it in place through biomechanical forces" (Ex. 3 at 26:24-27:10). Thus, the 234 patent teaches that polyester, which includes materials such as PET, imparts knot tie down or knot holding strength to a braid of UHMWPE and polyester. Thus, Arthrex's 234 Patent further shows that the differences are insubstantial because UHMWPE is described as a lubricous yarn that with bad knot properties, and similarly embodiments of the first fiber-forming materials are described as lubricous.

20. I understand that Arthrex has asserted that the differences between the first fiber-forming materials (if PE does not include UHMWPE) and UHMWPE are substantial because the purpose of UHMWPE in FiberWire is alleged to be to provide strength (Arthrex Br. at 11). I disagree with this statement because the 446 Patent describes embodiments in which the first set of yarns is lubricous and provides PE as an example of a lubricous yarn (Ex. 2 at 4:11-12). The UHMW PE in FiberWire is consistent with this description; FiberWire's UHMW PE is lubricous (Ex. 3 at 52:24-53:1). The 446 Patent also describes embodiments in which the claimed second fiber-forming yarns, including PET, are braided with the claimed first fiber-forming lubricous yarns, including PE, "to provide improved strength to the heterogeneous braid" (Ex. 2 at 4:33-36). FiberWire is consistent with this description; FiberWire's PET has a different lubricity than UHMWPE and adds improved strength to the FiberWire braid (Ex. 3 at 53:20-54:5; 46:16-47:5). Accordingly, PET increases certain knot strength properties, namely knot holding strength,[2] of

[2] I use the term "knot pull strength" to refer to the force at which a suture having a knot tied in it fails when tested in a tension test. I use the term "knot holding strength" to refer to the force at which a knot fails by slipping, elongating to a certain extent, or breaking, which can be tested generally in a procedure similar to Exs. 26 and 27. Knot holding strength is an indication

the braid of PET and UHMWPE because it reduces the tendency of the UHMWPE fibers to slip when tied in a knot. Thus, because FiberWire's UHMWPE is lubricous and FiberWire's PET imparts strength, FiberWire's construction is not the opposite of that described and claimed in the 446 Patent. Rather, it is consistent with the 446 Patent's teachings.

B. The Differences Between the Claimed First Fiber-Forming Materials And FiberWire's PE Are Insubstantial Based On the Function/Way/Result Analysis

21. It is my opinion that all of Arthrex's FiberWire™ and TigerWire™ suture products also infringe claims 1, 2, 8, 9, and 12 of the '446 Patent under the doctrine of equivalents because the differences, if any, between the claims, as I understand they may be construed by Arthrex, and Arthrex's FiberWire™ and TigerWire™ suture products are insubstantial under the function/way/result analysis.

22. I have used the "function/way/result" test to determine infringement of claims 1, 2, 8, 9, and 12 under the doctrine of equivalents. In particular, I have determined the function/way/result of the claim element that Arthrex contends is not literally satisfied and compared that to the function/way/result of UHMWPE in FiberWire™ and TigerWire™. My equivalency opinion is limited to nonbioabsorbable yarns as the first-forming material.

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of knot security. The 446 Patent describes another exemplary knot security test (Ex. 2 at 6:36-44).

64. It is my expert opinion and observation that the coating only appears on the surface of the braid.

I declare under penalty of perjury that the foregoing is true and correct.

Date Executed: September 1, 2006 /s/

Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a Massachusetts Corporation,

Plaintiff,

vs.

Arthrex, Inc., a Delaware Corporation,

Defendant.
_____/

COPY

CIVIL ACTION
NO. 04-12457 PBS

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."

And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?

And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.

One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.

I had Pearsalls, mainly through Brian, as being the manufacturing person --

Q. Brian Hallett?

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

A. Yes.

Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?

A. Yes.

Q. Yes?

A. Yes.

Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?

A. Yes.

Q. And when you say knot slippage, we're referring to this knot security test?

A. Yes.

Q. So are we using the terms knot slippage and knot security interchangeably here?

A. You are, yes.

Q. In your testimony?

A. Yes.

Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?

A. Yes.

Q. And your idea was to add the PET and to improve the knot security?

MR. SOFFEN: Objection; asked and answered. You've asked him the same thing multiple times. But you can answer.

A. I've lost count, it's been so many times, but the answer again is yes.

Q. Okay. And Dr. Burkhart said that was a killer idea?

A. What was a killer idea?

Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.

Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?

A. Yes.

Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?

A. Yes.

Q. And you tested that prototype?

A. Yes.

Q. And you said that that prototype had good knot strength?

A. Correct.

Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

Exhibit 6

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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MR. TAMBURO: Objection, vague.

THE WITNESS: This is general purpose polyethylene, which it provides the lubricity and as well as pliability and compliance, not ultra high molecular weight polyethylene.

BY MR. BONELLA:

Q. Okay, that wasn't my question. Listen to the question.

Did you understand that sentence to refer to all types of polypropylene?

MR. TAMBURO: Objection, vague.

THE WITNESS: The fiber-forming polypropylene, yes.

BY MR. BONELLA:

Q. All types, okay.

Did you understand -- do you see where it refers to PVDF?

A. Yes.

Q. Did you understand this paragraph to be referring to all types of polyvinylidene fluoride?

A. Yes.

Q. Okay. Do you see where it refers to PTFE in that paragraph?

A. Yes.

Q. Did you understand it to be referring to